

**REMARKS**

This Amendment is responsive to the Examiner's Office Action of May 13, 2009. By way of summary, Claims 5, 7-9, 11, 27, 28, 37 and 53-76 were pending in this application. Applicants have hereby amended Claims 27, 28 and 74, canceled Claim 75, and added new Claims 77-86. Thus, Claims 5, 7-9, 11, 27, 28, 37, 53-74 and 76-86 are presently pending in this application. Reconsideration of the application in view of the foregoing amendments and following remarks is respectfully requested.

**Claims 5, 7-9, 11, 27, 28, 37, 53-74 and 76 are Patentable Over the Applied Combination**

The Examiner rejected Claims 5, 7-9, 11, 27, 28, 37 and 53-76 under 35 U.S.C. § 103(a) as being obvious in view of the combination of U.S. Patent Nos. 6,544,249 B1, 6,464,724 B1 and 6,050,99 to Yu et al. ("Yu"), Lynch et al. ("Lynch") and Paraschac et al. ("Paraschac") respectively.

Applicants respectfully traverse these rejections and the Examiner's characterization of the cited references on the bases set forth below.

In this case, to advance prosecution, Applicants have amended Claims 27, 28 and 74, as shown above. Dependent Claim 75 has been canceled in view of the amendment to Claim 74. Applicants reserve the right to pursue any of the prior versions of the claims in one or more continuing applications and/or at a later date.

The Examiner asserted that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device and method of Yu with Lynch such that multiple implants were delivered, without removing the instrument from the eye between deliveries, to create additional flow channels and improve the flow of aqueous humor from an anterior chamber to a fluid outflow path of the eye and thereby reduce intraocular pressure in more severe cases. The Examiner further asserted that it would have been obvious to modify the combination of Yu and Lynch with Paraschac such that the multiple implants were arranged end to end within a tube to be serially dispensed by an actuator in a controlled manner.

Applicants' respectfully disagree with the Examiner's assertions. There is no evidence that Yu contemplated implanting multiple implants in the eye as set forth in Applicants' claims. To the contrary, Yu teaches away from such multiple implantations. Yu clearly teaches that a single implant (soluble microfistula tube) will achieve the stated objective of draining excess

aqueous humor from an eye to lower intraocular pressure (IOP). Yu additionally notes the importance of preventing over-drainage of aqueous humor. Yu states at column 1, lines approx. 40-45 (emphasis added):

**An object of the present invention is to provide a biological microfistula tube** subject to reduced rejection effects, that will lead to the formation of a microfistula for permanent or long-term aqueous fluid bypass, **with minimal overdraining**, and tending to impede wound healing processes and hence the closure of the drainage pathway.

Yu further states at column 2, lines 16-20 (emphasis added):

Consequently a microfistula tube size smaller than has been feasible with prior art devices or techniques may be employed, thereby **reducing the risk of overdraining the aqueous fluid**.

In view of the unambiguous teaching that a single implant will sufficiently lower IOP to treat glaucoma without creating a hypotonic condition and in view of the stated concern of preventing over-drainage, one skilled in the art would not have read Yu to teach or suggest the use of multiple implants, as the Examiner seems to suggest. In fact, one skilled in the art would read Yu to teach away from the use of multiple implants.

Lynch is directed to stent devices that are wholly contained within Schlemm's canal and do not extend into the anterior chamber of the eye. The primary purpose of these devices is "to expand the canal's dimensions and maintain its patency." See, for example, column 4, line approx. 28. Given Schlemm's canal's circumferential anatomy, Lynch provides a multi-site solution to address a particular problem.

Similarly, Paraschac is directed to multiple corneal implants to adjust corneal curvature and to correct vision abnormalities. See, column 1, lines 62-65. As one can imagine, without the use of multiple implants to maintain proper corneal symmetry, the resulting vision would be distorted. In Paraschac, the nature of the vision correction also requires multi-site solution to achieve its intended result.

It requires an untenable leap in logic to combine Yu, Lynch and Paraschac since the mere use of multiple implants in an eye, as taught by Lynch and Paraschac, would not lead one of ordinary skill in the art to place multiple drainage implants in the eye. The fact that Paraschac discloses the use of multiple implants in the cornea for optical symmetry does not provide any reason to use multiple implants to shunt aqueous humor from the anterior chamber. Similarly,

Lynch's teaching of using a series of stents along a length of Schlemm's canal to increase the canal's patency does not provide any reason to use multiple drainage implants to provide a plurality of drainage courses from the anterior chamber. Accordingly, the site-specific, application-specific teachings of Lynch and Paraschac do not apply to the aqueous drainage issues addressed by Yu and Applicants. Moreover, Yu clearly teaches away from the use of multiple implants for aqueous drainage from the anterior chamber of the eye. As such, the stated reasons to combine the references were predicated upon faulty logic.

The combination of Yu, Lynch and Paraschac thus is improper as the teaching of these references would clearly lead one skilled in the art away from making the suggested combination and there exists no sustainable reason in the record to combine these references together. Accordingly, Applicants submit that the Examiner has failed to establish a *prima facie* showing of obviousness.

The Examiner asserted, with respect to some of the rejected claims, at page 4, lines 9-16 of the Office Action:

... it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Yu et al., Lynch et al. and Paraschac et al. such that first and second implants were spaced at least 20 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art (*In re Boesch*, 617 F.2d 272,205 USPQ 215). Furthermore, it would have been obvious to try placing the first and second implants at least 20 degrees apart since it is obvious to choose from a finite number of identified, predictable solutions, with a reasonable expectation of success.

Applicants again respectfully disagree with this assertion by the Examiner. As noted above, the benefits of targeted implantation in an eye were neither known nor appreciated by others of skill in the art prior to Applicants' discovery thereof. For example, paragraph number [0251] of the Specification as filed states (emphasis added):

The programmed (also know as "Targeted") stent placement refers to the **intentional placement of a stent or stents at a particular location or locations in Schlemm's canal** for the purpose of providing a benefit in the form of more optimal outflow.

Applicants discovered the benefits achieved, in some cases, by providing a predetermined angular spacing, in one embodiment of at least 20 degrees, between implantation sites that was not recognized by others of skill in the art. Thus, among other reasons as discussed above, Applicants submit that the claims directed to this subject matter are not rendered obvious by the prior art, including the applied combination.

The Examiner further asserted, with respect to some of the rejected claims, at page 4, lines 9-16 of the Office Action:

... Yu et al. do not disclose the implant is placed in the uveal scleral [sic] outflow path of the eye. Lynch et al. teach aqueous humor is normally drained out of the eye through two different routes: "In the "uveoscleral" route, the fluid percolates between muscle fibers of the ciliary body. This route accounts for approximately ten percent of the aqueous outflow in humans. The primary pathway for aqueous outflow in humans is through the "canalicular" route that involves the trabecular meshwork and Schlemm's canal" (col 1, 11 35-48). Therefore, it would have been obvious to modify the combination of Yu et al., Lynch et al. and Paraschac et al. such that the first and second locations were in the uveal scleral outflow path of the eye as the uveal scleral outflow path of the eye is a well known normal anatomical drainage location and is a known alternative to the trabecular meshwork outflow path of the eye if the implant is unable to be implanted through the trabecular meshwork in a particular patient.

Applicants again respectfully disagree with this assertion by the Examiner for at least the reasons presented above. Thus, Applicants submit that the claims directed to this subject matter are not rendered obvious by the prior art, including the applied combination.

Turning now to the specific claims, independent Claim 5 is directed to an instrument for delivering implants for treating an ophthalmic condition and dispensing implants through a wall of Schlemm's canal, and recites, *inter alia* (emphasis added):

**a plurality of biocompatible implants positioned in the elongate body, each of said implants sized and shaped to convey aqueous humor from an anterior chamber of the eye to a fluid outflow path of the eye so as to reduce elevated intraocular pressure; and**

said elongate body further comprising an actuator that serially dispenses the implants from the elongate body for implanting in eye tissue.

**Application No.:** 10/634,213  
**Filing Date:** August 5, 2003

As discussed above, the combination of Yu, Lynch and Paraschac fails to render obvious at least these structural limitations. Thus, Claim 5 is patentable over the applied combination.

Claims 7-9 and 11 depend from Claim 5 and are patentable for at least the same reasons that Claim 5 is patentable, and because of the unique combination of limitations recited therein. Moreover, these claims define over the prior art, since the combination of limitations recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claims 5, 7-9 and 11 are in condition for allowance.

Independent Claim 27 is directed to a method of implanting a plurality of implants for treating an ocular disorder and recites, *inter alia* (emphasis added):

**conveying aqueous humor from an anterior chamber of the eye to a fluid outflow path of the eye using said first implant and said second implant;**  
**wherein said locations are determined by imaging collector channel locations.**

As discussed above, the combination of Yu, Lynch and Paraschac fails to render obvious at least these limitations. Thus, Claim 27 is patentable over the applied combination.

Claim 37 depends from Claim 27 and is patentable for at least the same reasons that Claim 27 is patentable, and because of the unique combination of limitations recited therein. Moreover, these claims define over the prior art, since the combination of limitations recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claims 27 and 37 are in condition for allowance.

Independent Claim 28 is directed to a method of implanting a plurality of implants for treating an ocular disorder and recites, *inter alia* (emphasis added):

**conveying aqueous humor from an anterior chamber of the eye to a fluid outflow path of the eye using said first implant and said second implant;**  
**wherein said locations are angularly spaced along Schlemm's canal by at least 20 degrees.**

As discussed above, the combination of Yu, Lynch and Paraschac fails to render obvious at least these limitations. Thus, Claim 28 is patentable over the applied combination. Moreover, this claim defines over the prior art, since the combination of limitations recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claim 28 is in condition for allowance.

Independent Claim 53 is directed to an instrument for delivering implants for treating an ophthalmic condition and dispensing implants through a wall of Schlemm's canal, and recites, *inter alia* (emphasis added):

**a plurality of biocompatible implants positioned in the elongate body, each of said implants sized and shaped to convey aqueous humor from an anterior chamber of the eye to a fluid outflow path of the eye so as to reduce elevated intraocular pressure; and**

said elongate body further comprising an actuator that serially dispenses the implants from the elongate body for implanting in eye tissue.

As discussed above, the combination of Yu, Lynch and Paraschac fails to render obvious at least these structural limitations. Thus, Claim 53 is patentable over the applied combination.

Claims 54-59 depend from Claim 53 and are patentable for at least the same reasons that Claim 53 is patentable, and because of the unique combination of limitations recited therein. Moreover, these claims define over the prior art, since the combination of limitations recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claims 53-59 are in condition for allowance.

Independent Claim 60 is directed to an instrument for delivering implants for treating an ophthalmic condition and dispensing implants through a wall of Schlemm's canal, and recites, *inter alia* (emphasis added):

**a plurality of biocompatible implants positioned in the elongate body, each of said implants sized and shaped to convey aqueous humor from an anterior chamber of the eye to a fluid outflow path of the eye so as to reduce elevated intraocular pressure; and**

said elongate body further comprising an actuator that serially dispenses the implants from the elongate body for implanting in eye tissue.

As discussed above, the combination of Yu, Lynch and Paraschac fails to render obvious at least these structural limitations. Thus, Claim 60 is patentable over the applied combination. Moreover, this claim defines over the prior art, since the combination of limitations recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claim 60 is in condition for allowance.

Independent Claim 61 is directed to an instrument for delivering implants for treating an ophthalmic condition and dispensing implants into tissue adjacent to a physiologic outflow pathway, and recites, *inter alia* (emphasis added):

**a plurality of biocompatible implants positioned in the elongate body, each of said implants sized and shaped to convey aqueous humor from an anterior chamber of the eye to the physiologic outflow pathway of the eye;**

wherein said elongate body further comprising an actuator that serially dispenses the implants from the elongate body for implanting in eye tissue.

As discussed above, the combination of Yu, Lynch and Paraschac fails to render obvious at least these structural limitations. Thus, Claim 61 is patentable over the applied combination.

Claims 62-65 depend from Claim 61 and are patentable for at least the same reasons that Claim 61 is patentable, and because of the unique combination of limitations recited therein. Moreover, these claims define over the prior art, since the combination of limitations recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claims 61-65 are in condition for allowance.

Independent Claim 66 is directed to a method of implanting a plurality of implants for treating an ocular disorder and recites, *inter alia* (emphasis added):

**providing a plurality of biocompatible implants that, when implanted, convey aqueous humor from an anterior chamber of the eye to a physiologic outflow pathway of the eye;**

**Application No.: 10/634,213**

**Filing Date: August 5, 2003**

utilizing said instrument to **deliver a first biocompatible implant** through a wall of a physiologic outflow pathway at a first location within the eye; and

utilizing said instrument to **deliver a second biocompatible implant** through a wall of said physiologic outflow pathway at a second location within the eye, without removing said instrument from the eye between said deliveries of said implants.

As discussed above, the combination of Yu, Lynch and Paraschac fails to render obvious at least these steps. Thus, Claim 66 is patentable over the applied combination.

Claims 67-73 depend from Claim 66 and are patentable for at least the same reasons that Claim 66 is patentable, and because of the unique combination of limitations recited therein. Moreover, these claims define over the prior art, since the combination of limitations recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claims 66-73 are in condition for allowance.

Independent Claim 74 is directed to a method of implanting a plurality of implants for treating an ocular disorder and recites, *inter alia* (emphasis added):

utilizing the instrument to **deliver a first implant** through eye tissue so as to place a portion of the first implant in a uveal scleral outflow path of the eye;

utilizing the instrument to **deliver a second implant** through eye tissue so as to place a portion of the second implant in the uveal scleral outflow path, without removing the instrument from the eye between the deliveries of the implants; and

**conveying aqueous humor** from an anterior chamber of the eye **to the uveal scleral outflow path using the implants.**

As discussed above, the combination of Yu, Lynch and Paraschac fails to render obvious at least these steps. Thus, Claim 74 is patentable over the applied combination.

Claim 76 depends from Claim 74 and is patentable for at least the same reasons that Claim 74 is patentable, and because of the unique combination of limitations recited therein. Moreover, these claims define over the prior art, since the combination of limitations recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

**Application No.:** 10/634,213  
**Filing Date:** August 5, 2003

Accordingly, Applicants respectfully submit that Claims 74 and 76 are in condition for allowance.

**New Claims 77-86 Define Over the Prior Art**

Applicants have added new Claims 77-86 to vary further the scope of protection. These claims are supported by the Application as originally filed, and no new matter has been introduced.

Independent Claim 77 is directed to an instrument for delivering a plurality of implants for treating an ocular disorder and recites, *inter alia* (emphasis added):

**a plurality of implants positioned in the elongate body, at least one of said implants being sized and shaped to convey aqueous humor from an anterior chamber of the eye to a physiologic outflow pathway of the eye so as to reduce elevated intraocular pressure; and**

**said elongate body further comprising an actuator that serially dispenses the implants from the elongate body such that a first implant is implanted at a first location in the eye and a second implant is implanted at a second location in the eye.**

At least these limitations are not taught or suggested by the applied references. Accordingly, Applicants submit that Claim 77 is patentable.

Claims 78-81 depend from Claim 77 and are patentable for at least the same reasons that Claim 77 is patentable, and because of the unique combination of limitations recited therein. Moreover, these claims define over the prior art, since the combination of limitations recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claims 78-81 are in condition for allowance.

Independent Claim 82 is directed to a method of delivering a plurality of implants for treating an ocular disorder and recites, *inter alia* (emphasis added):

**utilizing said instrument to deliver a first implant into eye tissue at a first location within the eye;**

**utilizing said instrument to deliver a second implant into eye tissue at a second location within the eye; and**

**Application No.:** 10/634,213  
**Filing Date:** August 5, 2003

**conveying aqueous humor from an anterior chamber of the eye to a physiologic outflow pathway of the eye using at least one of the implants.**

At least these steps are not taught or suggested by the applied references. Accordingly, Applicants submit that Claim 82 is patentable.

Claims 83-86 depend from Claim 82 and are patentable for at least the same reasons that Claim 82 is patentable, and because of the unique combination of limitations recited therein. Moreover, these claims define over the prior art, since the combination of limitations recited therein are not found in an individual prior art reference, or rendered obvious by a combination of prior art references.

Accordingly, Applicants respectfully submit that Claims 82-86 are in condition for allowance.

#### **No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

#### **Co-Pending Applications of Assignee**

Applicants wish to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

<b>Serial Number</b>	<b>Title</b>	<b>Filed</b>	<b>Attorney Docket No.</b>
10/889,254	OCULAR IMPLANT WITH ANCHOR AND THERAPEUTIC AGENT	July 12, 2004	GLAUKO.1C2C3

**Application No.:** 10/634,213  
**Filing Date:** August 5, 2003

<b>Serial Number</b>	<b>Title</b>	<b>Filed</b>	<b>Attorney Docket No.</b>
12/366,242	IMPLANT AND METHODS THEREOF FOR TREATMENT OF OCULAR DISORDERS	February 5, 2009	GLAUKO.1C2C3DV1
10/706,300	OCULAR IMPLANT WITH THERAPEUTIC AGENTS AND METHODS THEREOF	November 12, 2003	GLAUKO.1C3CP1
11/124,440	METHOD OF DELIVERING AN IMPLANT FOR TREATING AN OCULAR DISORDER	May 6, 2005	GLAUKO.1C4C2
11/841,967	THERAPEUTIC SHUNT DEVICE AND METHOD FOR TREATING GLAUCOMA	August 20, 2007	GLAUKO.1C4C10
12/366,565	OCULAR IMPLANT WITH ANCHOR AND METHODS THEREOF	February 5, 2009	GLAUKO.1C4C11
12/437,482	METHOD OF DELIVERING AN IMPLANT FOR TREATING AN OCULAR DISORDER	May 7, 2009	GLAUKO.1C4C12
12/354,610	OCULAR IMPLANT WITH ANCHORS AND METHODS THEREOF	January 15, 2009	GLAUKO.1CP1C1CC
10/950,175	IMPLANT WITH INTRAOCULAR PRESSURE SENSOR FOR GLAUCOMA TREATMENT	September 24, 2004	GLAUKO.5C1CP1
11/598,542	IMPLANT AND METHODS THEREOF FOR TREATMENT OF OCULAR DISORDERS	November 13, 2006	GLAUKO.011C1
12/111,033	SYSTEM FOR TREATING OCULAR DISORDERS AND METHODS THEREOF	April 28, 2008	GLAUKO.011C1C1
12/366,508	SELF-TREPHINING IMPLANT AND METHODS THEREOF FOR TREATMENT OF OCULAR DISORDERS	February 5, 2009	GLAUKO.011C1DV1
12/366,585	OCULAR IMPLANT DELIVERY SYSTEM AND METHODS THEREOF	February 5, 2009	GLAUKO.011C1DV2
11/836,106	DEVICES AND METHODS FOR TREATMENT OF OCULAR DISORDERS	August 8, 2007	GLAUKO.11CP1C1

**Application No.:** 10/634,213  
**Filing Date:** August 5, 2003

<b>Serial Number</b>	<b>Title</b>	<b>Filed</b>	<b>Attorney Docket No.</b>
11/836,112	DEVICES AND METHODS FOR TREATMENT OF OCULAR DISORDERS	August 8, 2007	GLAUKO.11CP1C2
11/084,314	OCULAR DISORDER TREATMENT IMPLANTS WITH MULTIPLE OPENINGS	March 18, 2005	GLAUKO.11CP2CP1
12/246,448	DRUG ELUTING OCULAR IMPLANT WITH ANCHOR AND METHODS THEREOF	October 6, 2008	GLAUKO.11CP3DV1
11/860,785	OCULAR IMPLANT WITH DOUBLE ANCHOR MECHANISM	September 25, 2007	GLAUKO.013C1DV1
11/455,598	IMPLANT DELIVERY SYSTEM AND METHODS THEREOF FOR TREATING OCULAR DISORDERS	June 19, 2006	GLAUKO.017C1
11/455,391	IMPLANT DELIVERY SYSTEM AND METHODS THEREOF FOR TREATING OCULAR DISORDERS	June 19, 2006	GLAUKO.017C2
11/332,746	FLUID INFUSION METHODS FOR OCULAR DISORDER TREATMENT	January 12, 2006	GLAUKO.020C1
11/653,815	COMBINED TREATMENT FOR CATARACT AND GLAUCOMA TREATMENT	January 16, 2007	GLAUKO.022C1
10/338,743	OCULAR IMPLANT WITH ANCHORING MECHANISM AND MULTIPLE OUTLETS	December 18, 2008	GLAUKO.035DV1
11/938,238	UVEOSCLERAL SHUNT AND METHODS FOR IMPLANTING SAME	November 9, 2007	GLAUKO.099A

### **Conclusion**

Applicants respectfully submit that the claims are in condition for allowance in view of the above remarks. Any remarks in support of patentability of one claim, however, should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully

**Application No.:** 10/634,213

**Filing Date:** August 5, 2003

traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although amendments may have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby. Applicants also reserve the right to later further contest whether a proper reason exists to combine these references as well as to later present further facts and arguments supporting the non-obviousness of the claimed subject matter.

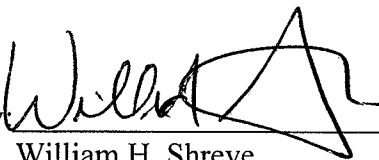
Applicants have made a good faith effort to respond to the outstanding Office Action. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is cordially invited to contact Applicants' attorney, at the telephone number below, to resolve any such issues promptly. Also, please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 13, 2009

By



William H. Shreve  
Registration No. 35,678  
Attorney of Record  
Customer No. 20995  
(949) 760-0404

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